UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NOT FOR PUBLICATION

SUPERNUS PHARMACEUTICALS, INC., Plaintiff, v. AJANTA PHARMA LIMITED and AJANTA PHARMA USA INC., Defendants.	Civ. No. 21-6964 (GC) **OPINION**
SUPERNUS PHARMACEUTICALS, INC., Plaintiff, v. TORRENT PHARMACEUTICALS LTD. and TORRENT PHARMA INC., Defendants.	Civ. No. 21-14628 (GC) **OPINION**

CASTNER, District Judge

THIS MATTER comes before the Court on the Joint Claim Construction and Prehearing Statement regarding U.S. Patent Nos. 8,298,580 (filed Dec. 17, 2010) ("the '580 Patent"), 8,663,683 (filed Aug. 27, 2012) ("the '683 Patent"), 8,877,248 (filed July 14, 2014) ("the '248 Patent"), 8,992,989 (filed Sept. 29, 2014) ("the '989 Patent"), 9,549,940 (filed Sept. 8, 2016) ("the '940 Patent"), 9,622,983 (filed Sept. 8, 2016) ("the '983 Patent"), and 10,314,790 (filed March 30, 2017) ("the '790 Patent") (collectively, the "patents in suit") submitted by Plaintiff Supernus

Pharmaceuticals, Inc. ("Plaintiff") and Defendants Ajanta Pharma Ltd. and Ajanta Pharma USA Inc. ("Ajanta"), and Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. ("Torrent") (collectively, "Defendants") pursuant to L. Pat. R. 4.3. (ECF No. 61.) On May 9, 2022, Plaintiff and Defendants filed opening briefs. (ECF Nos. 67, 68.) Plaintiff submitted the Expert Declaration of Mansoor A. Khan, R.Ph., Ph.D., with its opening brief. (*See generally* Opening Declaration of Mansoor A. Khan ("Opening Khan Decl."), ECF No. 68-2.) On July 1, 2022, Plaintiff and Defendants filed responsive briefs. (ECF Nos. 76, 77.) Plaintiff submitted another Declaration of Mansoor A. Khan, P.Ph., Ph.D., with its responsive brief. (*See generally* Responsive Declaration of Mansoor A. Khan ("Responsive Khan Decl."), ECF No. 77-1.)

The parties dispute five claim terms that appear in the patents in suit. (*See* Joint Prehr'g Stmt. Ex. A, ECF No. 61.) On July 21, 2022, pursuant to L. Pat. R. 4.6, the Court held a *Markman* hearing to construe the claim terms. (ECF No. 78.) The claim terms are construed below.

I. BACKGROUND

A. *Procedural Background*

This case arises out of Defendants' filing of Abbreviated New Drug Applications ("ANDAs") with the Food and Drug Administration ("FDA") to seek approval to market a generic version of the pharmaceutical product Trokendi XR® (hereinafter, "Trokendi"). (Joint Prehr'g Stmt. 1.) Plaintiff, the pharmaceutical company that holds the New Drug Application ("NDA") for Trokendi, alleges that Defendants' ANDAs infringe on the seven patents in suit, as well as three additional Trokendi patents, United States Patent Nos. 8,298,576 ("the '576 Patent"),

8,889,191 ("the '191 Patent"), and 9,555,004 ("the '004 Patent"), (collectively, the "Trokendi patents"). (*Id.* at 1; Compl. ¶¶ 1, 54–133, ECF No. 1.)[1]

To market and sell Trokendi, Plaintiff listed the Trokendi patents in the FDA's Approved Drug Products with Therapeutic Equivalence Applications, commonly known as the Orange Book. *See* 21 U.S.C. § 355(b)(1), (c)(2); (Compl. ¶ 28.) Thereafter, Defendants filed their ANDAs with the FDA to market generic versions of Trokendi. *See* 21 U.S.C. § 355(j)(1); (Compl. ¶¶ 39–42.) Accordingly, pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), Plaintiff initiated this suit against Defendants because Defendants requested to market the generic version of Trokendi prior to the expiration of the Trokendi patents. (Compl. ¶¶ 54–133.)

B. *The Patents in Suit*

All seven of the patents in suit are called "Sustained-Release Formulations of Topiramate," and they share the same specification.[2] ('580 Patent col. 1 l. 1–2, Compl. Ex. B, ECF No. 1-2; '683 Patent col. 1 l. 1–2, Compl. Ex. C, ECF No. 1-3; '248 Patent col. 1 l. 1–2, Compl. Ex. D, ECF No. 1-4; '989 Patent col. 1 l. 1–2, Ex. F, ECF No. 1-6; '940 Patent col. 1 l. 1–2, Compl. Ex. G, ECF No. 1-7; '983 Patent col. 1 l. 1–2, Compl. Ex. I, ECF No. 1-9; '790 Patent col. 1 l. 1–2, Compl. Ex. J, ECF No. 1-10; *see also* Markman Hr'g Tr. ("Tr.") 15:25–16:3, 60:1–60:5, ECF No. 87.)

Topiramate is a pharmaceutical product that has been approved for use as an "antiepileptic agent" to treat seizures and migraines under the trade name Topamax® (hereinafter, "Topamax").

---

[1] The Torrent and Ajanta Defendants agreed to consolidate their actions on December 17, 2021. (ECF No. 43.) Unless specified otherwise, citations refer to the docket in the consolidated action, *Supernus Pharmaceuticals, Inc. v. Ajanta Pharma Ltd et al.*, Civ. No. 21-6964 (D.N.J. 2021).

[2] When citing to the shared specification of the patents in suit, the Court cites to the '580 Patent. *See Gemalto S.A. v. HTC Corp.*, 754 F.3d 1364, 1366 & n.2 (Fed. Cir. 2014).

('580 Patent col. 1 l. 16–22.) Topamax is administered in "immediate release dosage form," which means that the "topiramate is rapidly absorbed with plasma drug concentrations peaking in approximately 2 hours." (*Id.* col. 5 l. 23–26.) This type of administration is "associated with a peak in plasma concentrations of the drug, and the fluctuations associated with the peaks and valleys of blood plasma levels of the drug are undesirable." (*Id.* col. 1 l. 49–53.)

The Trokendi patents address this problem by providing a "sustained release" of topiramate where the "sustained release formulation comprises an extended release (XR) component and an optional immediate release (IR) component." (*Id.* col. 2 l. 6–10, 24–27.)[3] With these sustained release formulations, the Trokendi patents aim to "reduc[e] in the frequency or severity of at least one side effect associated with the topiramate treatment," and "provide a sustained release formulation that can be administered orally once a day" without the associated side effects. (*Id.* col. 2 l. 11–19; Tr. 19:19–20:11.)

II. LEGAL STANDARD

The meaning and scope of patent claims are questions of law to be decided by the court. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996). "It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal citation and quotation marks omitted). "[T]here is no magic formula or catechism for conducting claim construction." *Id.* at 1324. Instead, the Court is free to attach the appropriate weight to appropriate sources "in light of the statutes and policies that inform patent law." *Id.* (citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). "Claim construction begins with the

[3] The claims and specification of the patents in suit refer to "extended release" and "XR" interchangeably, and "immediate release" and "IR" interchangeably. The Court does the same in this Opinion.

intrinsic evidence of the patent—the claims, the specification, and the prosecution history—and may require consultation of extrinsic evidence to understand the state of the art during the relevant time period." *Merck Sharp & Dohme Corp. v. Teva Pharms. USA, Inc.*, 2019 WL 943532, at *2 (D.N.J. Feb. 26, 2019); *see also Phillips*, 415 F.3d at 1317.

First, the court "looks to the words of the claims themselves, both asserted and nonasserted, to define the scope of the patented invention." *Vitronics Corp.*, 90 F.3d at 1582. The "words of a claim are 'generally given their ordinary and customary meaning,'" which is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips*, 415 F.3d. at 1312–13 (quoting *Vitronics Corp.*, 90 F.3d at 1582). A person of ordinary skill in the art ("POSA") "is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Id.* at 1313 (citing *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed. Cir. 1998)). Accordingly, "the claims themselves provide substantial guidance as to the meaning of particular claim terms," and a court may look to "the context in which a term is used in the asserted claim" and "other claims of the patent in question, both asserted and unasserted." *See id.* at 1314. "Differences among claims can also be a useful guide in understanding the meaning of particular claim terms. For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id.* at 1314–15 (internal citation omitted).

Second, the specification is "always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Vitronics Corp.*, 90 F.3d at 1582; *see also Phillips*, 415 F.3d at 1315 (noting that claims "are part of 'a fully

integrated written instrument,' and 'must be read in view of the specification, of which they are a part'") (citing *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996)). As the Federal Circuit put it, "[c]laims define and circumscribe, the written description discloses and teaches." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1347 (Fed. Cir. 2010). "Although words in a claim are generally given their ordinary and customary meaning, a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history." *Vitronics Corp.*, 90 F.3d at 1582. However, while "[t]he written description and other parts of the specification [] may shed contextual light on the plain and ordinary meaning [], they cannot be used to narrow a claim term to deviate from the plain and ordinary meaning unless the inventor acted as his own lexicographer or intentionally disclaimed or disavowed claim scope." *Aventis Pharms. Inc. v. Amino Chemicals Ltd.*, 715 F.3d 1363, 1373 (Fed. Cir. 2013).

Third, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman*, 52 F.3d at 980. "This history contains the complete record of all the proceedings before the [Patent and Trademark Office ("PTO")], including any express representations made by the applicant regarding the scope of the claim." *Vitronics Corp.*, 90 F.3d at 1582. "A patent's prosecution history, though less useful for claim construction purposes than the claim language and written description, plays various roles in resolving uncertainties about claim scope." *Mass. Inst. of Tech. v. Shire Pharms., Inc.*, 839 F.3d 1111, 1118 (Fed. Cir. 2016) (internal quotation marks and citations omitted). The prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention. *Phillips*, 415 F.3d at 1317. For example, the prosecution history may "limit[] the interpretation of claim terms so as to exclude

any interpretation that was disclaimed during prosecution." *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995) (citation omitted). To limit the scope of a claim based on prosecution statement, the patentee must have made "clear and unmistakable prosecution arguments limiting the meaning of a claim term in order to overcome a rejection." *SanDisk Corp. v. Memorex Prod., Inc.*, 415 F.3d 1278, 1286 (Fed. Cir. 2005) (citing *Omega Eng'g, Inc, v. Raytek Corp.*, 334 F.3d 1314, 1324 (Fed. Cir. 2003)). However, "because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Phillips*, 415 F.3d at 1317.

Finally, in some cases, the "district court will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 331 (2015). "Extrinsic evidence consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. However, "[i]n those cases where the public record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper." *Vitronics Corp.*, 90 F.3d at 1583. "When an analysis of *intrinsic* evidence resolves any ambiguity in a disputed claim term, it is improper to rely on extrinsic evidence to contradict the meaning so ascertained." *Intel Corp. v. VIA Techs., Inc.*, 319 F.3d 1357, 1367 (Fed. Cir. 2003) (emphasis in original). "Extrinsic evidence [] cannot be used to alter a claim construction dictated by a proper analysis of the intrinsic evidence." *On-Line Tech. v. Bodenseewerk Perkin-Elmer*, 383 F.3d 1133, 1139 (Fed. Cir. 2004) (citations omitted).

III. CLAIM CONSTRUCTION

A. *Preliminary Matters*

The parties agree that the patents in suit share the same specification, (Tr. 15:25–16:3, 60:1–60:5), and "originate from the same parent application," (*id.* at 60:1–3; *see also id.* at 16:4–10). The patents in suit also share the same inventors. (*See* '580 Patent, at [75]; '683 Patent, at [75]; '248 Patent, at [72]; '989 Patent, at [72]; '940 Patent, at [72]; '983 Patent, at [72]; '790 Patent, at [72]). The parties also agree that, because the patents in suit are part of the same patent "family," the "prosecution history of related patents is relevant to all patents in that family." (*Id.* at 16:4–6; 17:1–13; 59:25–60:11); *see also Gemalto S.A. v. HTC Corp.*, 754 F.3d 1364, 1371 (Fed. Cir. 2014) ("When multiple patents derive from the same initial application, the prosecution history regarding a claim limitation in any patent that has issued applies with equal force to subsequently issued patents that contain the same claim limitation") (quoting *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 980 (Fed. Cir. 1999)) (alteration removed). Accordingly, the Court uses prosecution histories of other Trokendi patents, the '191 and '576 Patents, in this claim construction.

The parties also agree that, while the disputed claim terms appear in multiple patent claims within the patents in suit, their constructions should be uniform. (Tr. 17:14–22; 60:1–5.) Thus, unless noted otherwise, the Court's constructions of the disputed claim terms apply across the patents in suit. *See Omega Eng'g, Inc.*, 334 F.3d at 1334 ("[W]e presume, unless otherwise compelled, that the same claim term in the same patent or related patents carries the same construed meaning.").

B. *Person of Ordinary Skill in the Art*

Claims are construed from the vantage point of a person of ordinary skill in the art ("POSA") at the time of the invention. *Phillips*, 415 F.3d at 1313. Before the Court construes the

claims in light of the specification, it must establish the level of skill that a POSA possessed at the time of the invention. *Supernus Pharms., Inc. v. Actavis Inc.*, 2016 WL 901837, at *2 (D.N.J. Mar. 9, 2016) (citing *AllVoice Computing PLC v. Nuance Commc'ns, Inc.*, 504 F.3d 1236, 1240 (Fed. Cir. 2007)). Here, Plaintiff provided the following definition for a POSA:

> [A] person of ordinary skill in the art here is someone in the 2006 time frame with at least a Bachelor of Science degree in Pharmaceutical Sciences or a related field, approximately three to five years of experience in drug delivery technology or a related field, and working knowledge regarding pharmacokinetics (or a person of commensurate education and experience).

(Pl.'s Opening Br. 6, ECF No. 68.) At the *Markman* hearing, Defendants agreed to this definition. (Tr. 6:22–7:3.) Accordingly, the Court defines a POSA according to the un-objected to definition provided by Plaintiff, *see AllVoice Computing PLC*, 504 F. 3d at 1240 (adopting one party's POSA definition where the other party "did not pose a different definition nor dispute the above definition"), and construes the claims from the vantage point of this POSA.

C. *Claim Construction*

The parties dispute the construction of five "term groups." (Defs.' Opening Br. 11–28, ECF No. 67; Pl.'s Opening Br. 6–15.) The Court examines each term group below.

1. Term Group No. 1: "Release(d)(s) Topiramate in a Continuous Manner" or "Released . . . Continuously"

Claim Term	"Release topiramate in a continuous manner" "Releases topiramate in a continuous manner" "Released topiramate in a continuous manner" "Released . . . continuously"
Plaintiff's Proposed Construction	Requires no construction — plain and ordinary meaning "Release topiramate in a manner without interruption" "Releases topiramate in a manner without interruption" "Released topiramate in a manner without interruption" "Released . . . without interruption"

Defendants' Proposed Construction	"Release topiramate without interruption, though the rate of release may be variable" "Releases topiramate without interruption, though the rate of release may be variable" "Released topiramate without interruption, though the rate of release may be variable" "Released topiramate without interruption, though the rate of release may be variable"
Court's Construction	Requires no construction — plain and ordinary meaning "Release topiramate in a manner without interruption" "Releases topiramate in a manner without interruption" "Released topiramate in a manner without interruption" "Released . . . without interruption"

The above terms appear in the '580 Patent, claims 1, 3–11, 13–17, 19–26, 28–30; the '248 Patent, claims 1–12, 14–20; the '683 Patent, claims 1, 2, 4–15, 17–20, 23, 24; the '989 Patent, claims 14, 18–20; the '940 Patent, claims 14, 18–20; and the '983 Patent, claims 13, 17–29. (Joint Prehr'g Stmt. Ex. A.) At the *Markman* hearing, Defendants agreed to "adopt [P]laintiff's construction for this; with the proviso that [Defendants] are not . . . waiving [their] argument that the rate of release could be variable." (Tr. 69:12–19.) Thus, the Court adopts Plaintiff's construction and acknowledges that Defendants have not waived this argument. (*Id.* at 70:5–8.)

2. Term Group No. 2: "Immediately and Continuously"

Claim Term	"Immediately and continuously"
Plaintiff's Proposed Construction	Requires no construction — plain and ordinary meaning "Without delay and without interruption"
Defendants' Proposed Construction	"Without delay and without interruption, though the rate of release may be variable"
Court's Construction	Requires no construction — plain and ordinary meaning "Without delay and without interruption"

a. Parties' Arguments

The parties agree that "immediately" means "without delay," but dispute whether the construction of "continuously" also requires the phrase, "though the release rate may be variable." (Pl.'s Responsive Br. 10, ECF No. 77; Defs.' Responsive Br. 9, ECF No. 76.) Plaintiff argues that "continuous" means "without interruption" with no additional language because, during prosecution of the '191 Patent, the applicants stated that "continuous" means "simply 'without interruption.'" (Pl.'s Opening Br. 8–9 (citing '191 Patent, U.S. Appl. No. 12/926,936 (hereinafter, "'191 Patent Prosecution History"), Amendment and Reply under 37 C.F.R. § 1.116, Remarks 10 (Apr. 2, 2013)), Decl. of Richard F. Kurz in Support of Pl.'s Opening Br. ("Kurz Decl.") Ex. 2, ECF No. 68-1.) The applicant also stated, "[t]he term 'continuous' does not define the amount of drug release, only the *manner* in which it is released (*i.e.*, "continuously")." (*Id.* (citing '191 Patent Prosecution History, Remarks 10) (emphasis in original).) Thus, Plaintiff argues that "Defendants cannot reasonably rely on these statements to add extraneous 'variability' concepts to the definition of 'continuous' release." (*Id.* at 9.)[4]

Defendants assert that the patentee's "agreement" to the patent examiner's statement, "[t]he term 'continuous manner' does not require the amount be release at any particular level; only that there be some release," ('191 Patent Prosecution History, Remarks 10), acknowledged that the rate of release may be variable, (*see* Defs.' Opening Br. 12). Defendants further contend

[4] Plaintiff also points to extrinsic evidence, including dictionary definitions and the expert report of Mansoor A. Khan, R.Ph., Ph.D., to support its proposed construction. (*Id.* at 7–8; *see also* MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 270 (11th ed. 2004), Kurz Decl. Ex. 3, ECF No. 68-1; Opening Khan Decl.) At the *Markman* hearing, Plaintiff noted that the Court does not need to rely on the extrinsic evidence to construe these terms. (Tr. at 11:20–25.) Thus, for this term and the remaining terms, the Court does not rely on extrinsic evidence because it finds the terms clear based on intrinsic evidence alone. *See Intel Corp.*, 319 F.3d at 1367.

that "[a] skilled artisan would be aware of at least the problems with achieving a zero-order release rate (*i.e.*, wherein the rate is not variable)," and "[p]rior art had disclosed the problem with achieving a zero-order (non-variable) release rate." (*Id.*; Defs.' Responsive Br. 3–4.) Thus, Defendants argue, "absent a clear claim element indicating that the claimed formulation has a constant rate of release, the claims should be construed to account for and permit the variability that was known in the prior art." (Defs.' Opening Br. 12 (citing *Nat'l Oilwell Varco, L.P. v. Auto-Dril, Inc.*, Civ. No. 09-85, 2011 WL 3648532, at *17 (E.D. Tex. Aug. 16, 2011).)

b. Court's Construction

The Court begins with the claim language. *See Vitronics Corp.*, 90 F.3d at 1582. The term "immediately and continuously" appears in the '989 Patent, claims 14, 18–20; the '940 Patent, claims 14, 18–20; and the '983 Patent, claims 13, 17–29. (Joint Prehr'g Stmt. Ex. A.) These claims cover "sustained release formulation[s] of topiramate," where the topiramate "is released **immediately and continuously** . . . ," as well as methods to administer these formulations. ('989 Patent col. 21 l. 1–35, col. 22 l. 22–col. 23 l. 7; '940 Patent col. 21 l. 59–col. 22 l. 27, col. 23 l. 14–col. 24 l. 33; '983 Patent col. 21 l. 32–67, col. 22 l. 55–col. 24 l. 44) (disputed term bolded).)

The parties' agreed upon construction of "immediately" as "without delay" is consistent with the plain language of the claims and the prosecution history of the '576 Patent. In the prosecution history, the applicants distinguished their invention from the prior art by stating that "[t]he claim invention, by contrast, does not *delay* release of topiramate, but rather *extends* the duration of its release. In other words, according to the present invention, the release of topiramate starts immediately upon administration . . ." ('576 Patent, U.S. Appl. No. 11/941,475 (hereinafter, "'576 Patent Prosecution History"), Amendment and Reply under 37 C.F.R. § 1.111, Applicant Remarks 28 (July 27, 2010), Decl. of Joseph H. Kim in Support of Defs.' Opening Br. ("Kim

Decl.") Ex. 2, ECF No. 67-3 (emphasis in original).) Accordingly, the Court agrees with the parties that "immediately" means "without delay."

Turning to "continuously," the Court agrees with Plaintiff that "continuously" means "without interruption." The claims themselves do not indicate that "continuously" should include the phrase "though the rate of release may be variable;" they state only that the "topiramate" is released "immediately and continuously." (*E.g.*, '989 Patent col. 21 l. 1–35.)

Next, Defendants argue that the specification demonstrates that the rate of release can be variable. (Defs.' Responsive Br. 4–5.) They point to an embodiment where there is an "instantaneous" dissolution of topiramate from the outside coating of a capsule, followed by a "sustained release" of the rest of the topiramate from the inside coating of the capsule. (*See* '580 Patent col. 11 l. 8–12.) However, while this embodiment teaches a particular embodiment of the overall invention, it does not further explain or define the meaning of the word "continuously." (*See* col. 10 l. 65–col. 11 l. 13.) The "Definitions" section does not include the term "continuous" or "continuously," (*see id.* col. 3 l. 30–col. 4 l. 43), and the specification does not otherwise define this term, (*see generally id.*). Thus, nothing in the specification "intentionally disclaim[s] or disavow[s] claim scope," as is required for the Court to adopt a construction outside of the plain and ordinary meaning of a term. *See Aventis Pharms. Inc.*, 715 F.3d at 1373; *see also Texas Instruments Inc. v. U.S. Int'l Trade Comm'n*, 988 F.2d 1165, 1171 (Fed. Cir. 1993) ("Courts can neither broaden nor narrow claims to give the patentee something different than what he has set forth.") (quoting *Autogiro Co. of Am. v. United States*, 384 F.2d 391, 396 (Ct. Cl. 1967)) (alteration omitted).

Further, the prosecution history supports Plaintiff's construction. In the prosecution of the '191 Patent, the patentee noted that "continuous" meant "*simply*" "without interruption." ('191

Patent Prosecution History, Remarks 10 (emphasis added).) Defendants' argument about the prosecution history, that the patentee's agreement to the statement, "[t]he term 'continuous manner' does not require the amount be released at any particular level; only that there be some release," means that "continuous" includes the "variable rate of release" language, is unpersuasive. (*See* Defs.' Opening Br. 12.) When read in context, the patentee further stated that "[t]he term 'continuous' does not define the amount of drug release, only the *manner* in which it is released (*i.e.*, "continuously"). ('191 Patent Prosecution History, Remarks 10 (emphasis in original).) The latter statement supports Plaintiff's construction — specifically that the "amount of drug release" is a function of the "rate of release,"[5] and it does not refer to the manner in which it is released, which is "continuous."

Thus, the construction of "continuously" as "without interruption" needs no further construction because its plain and ordinary meaning is clear, and nothing "clearly stated in the patent specification or file history" demonstrates that the patentee intended to "use [this term] in a manner other than [its] ordinary meaning." *See Vitronics Corp.*, 90 F.3d at 1582.

Finally, the Court notes that, like the parties' resolution with "release topiramate in a continuous manner," Defendants have not waived their argument that the release rate may be variable, *see supra* III.C.1, as this may be relevant in determining infringement, *see Lazare Kaplan Int'l, Inc. v. Photoscribe Techs., Inc.*, 628 F.3d 1359, 1376 (Fed. Cir. 2010); *Biotec Biologische Naturverpackungen GmbH & Co. KG v. Biocorp, Inc.*, 249 F.3d 1341, 1349 (Fed. Cir. 2001). The Court does not decide this at the claim construction stage, however, where the Court "should not

[5] The shared specification of the patents in suit defines "rate of release" or "release rate" as a function of "the quantity of drug released from a dosage form per unit time, e.g., milligrams of drug released per hour (mg/hr) or a percentage of a total drug dose released per hour." ('580 Patent col. 3 l. 53–57.)

resolve questions that do not go to claim scope, but instead go to infringement." *Eon Corp. IP Holdings LLC v. Silver Spring Networks, Inc.*, 815 F.3d 1314, 1319 (Fed. Cir. 2016). Thus, any disputes regarding whether certain processes (*e.g.*, those with or without variable rates of releases) are "continuous" are appropriately submitted to the finder of fact at the infringement stage. *See Biotech*, 249 F.3d at 1349 (rejecting the argument that "the district court 'failed to discharge its duty under *Markman*' when the court declined to construe 'melting'" because the "issue in dispute was the application of the melting step in the accused process, a factual question of infringement"); *Lazare*, 628 F.3d at 1375–76 (rejecting the argument that the district court failed to construe the scope of the term "positional accuracy of placement" because "the parties did not dispute the construction of the claim but rather the proper test to determine infringement, which is a factual question appropriate for the jury").

3. Term Group No. 3: "Immediate Release"

Claim Term	"Immediate release"
Plaintiff's Proposed Construction	Requires no construction — plain and ordinary meaning "Releases greater than or equal to about 80% of the pharmaceutical agent in less than or equal to about 1 hour"
Defendants' Proposed Construction	"Characterized by measured release of topiramate without delay and release of 80% or more of the topiramate contained in the immediate release component within 1 hour"[6]
Court's Construction	"Releases greater than or equal to about 80% of the pharmaceutical agent in less than or equal to about 1 hour"

a. Parties' Arguments

Plaintiff asserts that "[t]he specification expressly defines 'immediate release formulation'" and "[t]his explicit definition controls." (Pl.'s Opening Br. 9–10 (citing *Martek*

[6] In their original submissions, Defendants' proposed construction also included "after administration of the dosage form" after "within 1 hour." (*See* Joint Prehr'g Stmt. Ex. A.) At the *Markman* hearing, the parties agreed that Defendants would remove this phrase from their proposed construction. (Tr. 70:22–72:10.)

Biosciences Corp. v. Nutrinova, Inc., 579 F.3d 1363, 1381 (Fed. Cir. 2009)).) According to Plaintiff, "for Defendants to so drastically narrow the scope of 'immediate release'—an unambiguous term explicitly defined in the specification—they would have to identify 'disavowing actions or statements made during prosecution [that are] both clear and unmistakable." (Pl.'s Responsive Br. 6 (quoting *Omega Eng'g, Inc.*, 334 F.3d at 1325–26) (alteration in original).)

Defendants assert that Plaintiff's construction "can inform, but it's not a verbatim construction or definition," (Tr. 73:16–18; *see also* Defs.' Responsive Br. 6), because it relies on the definition for "immediate release *formulation*," but here, the term refers to "immediate release *component(s)*." (Defs.' Opening Br. 13–14 (emphases added).) Defendants propose the following modifications to Plaintiff's proposed construction:

First, Defendants argue that including "without delay" will clarify when the "immediate release component [is] being administered," (*See* Tr. 72:17–20; Defs.' Opening Br. 14 (citing '576 Patent Prosecution History, Applicant Remarks 28 and '580 Patent col. 11 l. 4–12), and make the construction of "immediate" in "immediate release" consistent with "immediately" in "immediately and continuously," (*see supra* III.C.2; Tr. 77:11–78:4.)

Second, Defendants assert that the construction of "immediate release" should specify that the "pharmaceutical agent" is "topiramate contained in the immediate release component." (Defs.' Opening Br. 15–18.) Defendants argue that the intrinsic evidence shows that "immediate release" refers to the "immediate release of a topiramate-containing component." (*See* Defs.' Opening Br. 17–18.) Defendants cite the claims themselves (*id.* at 16–17), which refer to the "immediate release" component as "topiramate-containing," ('580 Patent col. 20 l. 26–27; '248 Patent col. 20 l. 23–24; '989 Patent col. 21 l. 9–10; '940 Patent col. 22 l.1–2; '983 Patent col. 21 l. 41–42; '790

Patent col 20 l. 44–45), or as having "topiramate contained therein," ('683 Patent col. 20 l. 30–32). Defendants also cite the specification and prosecution history, which refer to "immediate release topiramate-containing component[s]." (Defs.' Opening Br. 17–18 (citing '580 Patent col. 1 l. 15–46 and '576 Patent Prosecution History, Amendment and Reply under 37 C.F.R. § 1.114, Applicant Remarks 22–23 (Mar. 28, 2011), Kim Decl. Ex. 3, ECF No. 67-4 and '191 Patent Prosecution History, As-Filed Specification ¶ [0021] (Dec. 17, 2010), Kim Decl. Ex. 14, ECF No. 67-15).)

Third, Defendants argue that the term "immediate release" requires the topiramate to be released "within one hour," not "less than or equal to *about* one hour." (*Id.* at 18.) Defendants argue that, because the patentee "chose not to include 'about' as a qualifier to the descriptions of the IR component release profiles while including it as a qualifier to the descriptions of the XR component release profiles," the patentee did not want "about" to modify the immediate release component release profiles. (*Id.* at 19.)[7]

b. Court's Construction

This term appears in the patents in suit as an "immediate release" component in a "sustained release formulation." The term appears in the '580 Patent, claims 1, 3–11, 13–17, 19–26, 28–30; the '683 Patent, claims 1–2, 4–15, 17–20, 23–24; the '248 Patent, claims 1–12, 14–20; the '989 Patent, claims 14, 18–20; the '940 Patent, claims 14, 18–20; the '983 Patent, claims 13, 17–29; and the '790 Patent, claims 1–10, 12–24. (Joint Prehr'g Stmt. Ex. A.) Specifically, the term appears in claims covering sustained release formulations comprising an extended release

[7] Defendants also include in their proposed claim construction that "immediate release" is "characterized by measured release of topiramate . . . ." (*See* Joint Prehr'g Stmt. Ex. A.) However, their briefs do not explain what they mean by "measured release" and how this language is necessary in the construction of "immediate release." (*See generally* Defs.' Opening Br.; Defs.' Responsive Br.) Thus, the Court does not consider this in Defendants' proposed construction.

topiramate-containing component or components and optionally, "an **immediate release** (IR) topiramate containing component," (*see* '580 Patent col. 20 l. 25–27; '248 Patent col. 20 l. 22–24; '989 Patent col. 21 l. 8–10; '940 Patent col. 21 l 67–col. 22 l. 2; '983 Patent col. 21 l. 40–42; '790 Patent col 20 l. 43–45) (disputed term bolded), or non-optionally, "an **immediate release** (IR) component, wherein 80% of the topiramate contained therein is released in vitro in not more than 1 hour," (*see* '683 Patent col. 20 l. 30–32 (disputed term bolded).)

The specification defines "immediate release formulation" as "a formulation that releases greater than or equal to about 80% of the pharmaceutical agent in less than or equal to about 1 hour." ('580 Patent col. 3 l. 33–35.)

The Court adopts Plaintiff's construction and finds the specification's definition of "immediate release formulation" instructive to construe "immediate release." First, there is a presumption "that the same phrase in different claims of the same patent should have the same meaning . . . , overcome only if 'it is clear' that the same phrase has different meanings in different claims." *In re Varma*, 816 F.3d 1352, 1363 (Fed. Cir. 2016) (quoting *Fin Control Sytems Pty, Ltd. v. OAM, Inc.*, 265 F.3d 1311, 1318 (Fed. Cir. 2001)). Here, Defendants have not pointed to a reason why "immediate release" should have different meanings for "immediate release formulation" and "immediate release components." *See id.* at 1363–64. Rather, at the *Markman* hearing, Defendants agreed that "immediate release" is its own term of art in the industry and agree that it "requires a release profile where at least 80% is released within one hour." (*See* Tr. 38:4–14, 76:18–77:3; Defs.' Opening Br. 14.)

Second, the definition of "sustained release" is helpful in construing "immediate release." The specification defines "sustained release" as "release of a pharmaceutical agent in a continuous manner over a prolonged period of time." ('580 Patent col. 3 l. 44–46.) By comparison, it defines

"immediate release formulation" as "a formulation that releases greater than or equal to about 80% of the pharmaceutical agent in less than or equal to one hour," (*id.* col. 3 l. 33–35). Comparing these definitions shows that the specification describes the type of release ("immediate" or "sustained") in the same terms: by how the "pharmaceutical agent" is released over a specified period of time. (*See id.* col. 3 l. 33–35, 44–46.)

Third, the phrases that Defendants propose to be inserted in the construction of "immediate release" are not supported by the claims, specification, or prosecution history. The Court will not construe "immediate release" to include the phrase "without delay" for the purpose of being consistent with the construction of "immediately and continuously." (*See supra* III.C.2.b.) While "the same claim term in the same patent or related patents carries the same construed meaning," *Omega Eng'g, Inc.*, 334 F.3d at 1334, here, "immediately" in the context of "immediately and continuously" and "immediate release" is not the same claim term. As noted above, the parties agree that "immediate release," is a term of art in the industry, distinct from the term "immediately and continuously." (*See* Tr. 38:4–14, 76:18–77:3.) Further, the terms "immediate release" and "immediately and continuously" are used in different contexts within the claims. "Immediately and continuously" appears in the claim preamble to describe how the "sustained release formulation" is released, (*see, e.g.*, '989 Patent col. 19 l. 41), while "immediate release" describes "topiramate-containing component(s)" contained in the sustained release formulation, (*id.* col. 19 l. 47–48). Recognizing that, in construing a claim, a POSA is deemed to read the term in the context of the claim it appears, *see Bradium Techs. LLC v. Iancu*, 923 F.3d 1032, 1042–43 (Fed. Cir. 2019) (citing *Phillips*, 415 F.3d at 1313), the different contexts of "immediate release" and "immediately and continuously" further demonstrate that these are two distinct terms, *see, e.g.*, *Comaper Corp. v. Antec, Inc.*, 596 F.3d 1343, 1348–49 (Fed. Cir. 2010) (construing "drive bay"

and "drive bay slot" as two distinct terms, based on "the intrinsic evidence support[ing] . . . that 'drive bay' and 'drive bay slot' have different meanings"). Thus, despite including the term "without delay" in the construction of "immediately and continuously," the Court will not do so here absent a clear intention that the patentee intended to include this limiting phrase to the term "immediate release." *See Aventis Pharms. Inc.*, 715 F.3d at 1373.

Additionally, the Court rejects Defendants' argument to remove the term "about" from the definition, which would "narrow [the] claims to give the patentee something different than what he has set forth." *See Texas Instruments Inc.*, 988 F.2d at 1171 (citation omitted). The specification clearly states that the term "about" "account[s] for variations, which can arise from inaccuracies in measurement inherent and understood by those of ordinary skill in the chemical and pharmaceutical arts." ('580 Patent, col. 6 l. 25–29.) Accordingly, where the patent states how a POSA would understand the term "about," no further construction of this term is needed. *See Merck & Co., Inc. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1369–70 (Fed. Cir. 2005) (noting that "about" should be given its plain meaning of "approximately" unless clearly defined otherwise in the specification).

Further, the Court rejects Defendants' argument that "pharmaceutical agent" should be replaced with "the topiramate contained in the immediate release component." (*See* Defs.' Opening Br. 16–18.) The claims and the specification both state that the immediate release components may include other agents in addition to topiramate. (*E.g.*, '580 Patent col. 20 l. 25–49 (describing claim 1, which states that the "immediate release (IR) topiramate containing component compris[es] . . . a complexing agent . . . and/or an enhancing agent . . . ."); '248 Patent col. 20 l. 25–46 (stating the same); '580 Patent col. 8 l. 14–28 (in describing the "topiramate-containing beads of the present invention," noting, "[t]he beads may further comprise other

pharmaceutically active agents suitable for use in combination with topiramate for treatment or prevention of a pathological condition"); *id.* col. 9 l. 46–51 (describing an embodiment where an "EIR [enhanced immediate release] composition comprises a highly soluble complex of topiramate with a complexing agent that is represented by, but not limited to, cyclodextrins . . ."); *id.* col. 17 l. 2–col. 18 l. 21 (describing examples 3 and 4, where topiramate enhanced immediate release beads contain "non-complexing enhancers" and "micronized particles"). Thus, Defendants' proposed construction would limit the scope of "immediate release" to specify that "topiramate" is released, when the claims and specification indicate that other agents may also be released. The Court will not construe this term so narrowly. *See Aventis Pharms. Inc.*, 715 F.3d at 1373.

Finally, to specify "topiramate" instead of "pharmaceutical agent" would render the remaining words in the claims redundant. The claims themselves already include a phrase to clarify that the "release" refers to "the topiramate contained therein," (*e.g.*, '683 Patent col. 20 l. 30–32), or "an immediate release (IR) topiramate containing component . . . wherein all of the components release topiramate in a continuous manner . . . ," (*e.g.*, 580 Patent, col. 20 l. 26–27, 50–51). Thus, where the claims specifically refer to the "release" of the "topiramate containing component," or the "topiramate contained therein," the Court does not need to construe the term "immediate release" to also include that reference. *See Merck*, 395 F.3d at 1372 (noting that a "claim construction that gives meaning to all terms of the claim is preferred over one that does not do so"). Accordingly, the Court adopts Plaintiff's proposed construction of "immediate release."

4. Term Group No. 4: "Extended Release (XR) Component(s)" and "Extended Release Topiramate-Containing Component(s)"

Claim Terms	"Extended release (XR) component" or "extended release component" "Extended release (XR) topiramate-containing component(s)" or "extended release topiramate-containing component(s)"
Plaintiff's Proposed Construction	Requires no construction — plain and ordinary meaning "A component that releases pharmaceutical agent over a prolonged period of time" "A component or components that release topiramate over a prolonged period of time"
Defendants' Proposed Construction	"An extended release topiramate-containing component which is not an immediate release component"
Court's Construction	"A component that releases topiramate in a continuous manner and is adjusted in such a way that 80% of the active ingredient is released in vitro in the predetermined period of time"

a. Parties' Arguments

Plaintiff argues that the prosecution history and specification support its construction that "extended release component" means "a component that releases a pharmaceutical agent over a prolonged period of time." (Pl.'s Opening Br. 12–14.) During prosecution, the applicants told the Patent Office that "'[e]xtended' release formulations release drug *in vivo* over a prolonged period of time (*e.g.*, greater than 4, 12, 16, or even 24 hours) measured from administration," ('191 Patent Prosecution History, Amendment and Reply under 37 C.F.R. § 1.116, Remarks 9 (Mar. 6, 2013), Kurz Decl. Ex. 5), and that "'extended release' coatings comprise 'extended release' polymers, which are designed to dissolve over an 'extended' period at a relatively constant rate," ('576 Patent Prosecution History, Amendment and Reply Under 37 C.F.R. § 1.111, Remarks 28 n.2 (July 27, 2010), Kurz Decl. Ex. 6). (*See* Pl.'s Opening Br. 12–13; Pl.'s Responsive Br. 12.) Plaintiff asserts that these remarks "clearly convey to a POSA that 'extended release' means release over an extended or prolonged period of time." (Pl.'s Opening Br. 13.)

Defendants argue that their construction of "extended release component" is appropriate because "immediate release components" and "extended release components" "are distinct from one another." (Defs.' Opening Br. 21–24.) Defendants further assert that, under Plaintiff's construction, "a single component could be both an XR component and an IR component as long as the component releases topiramate over a span of time greater than an hour," *e.g.*, "a drug product with a topiramate component that continuously releases 99% of the component within the first fifteen minutes and the remaining 1% of the component over the next five hours would be both an IR component and an XR component under Plaintiff's proposed construction." (*Id.* at 24.)

b. Court's Construction

Beginning with the claim language, the terms "extended release" or "XR" components appear in the seven of the patents in suit as "extended release" components that comprise "[a] sustained release formulation of topiramate comprising topiramate as an active ingredient . . . ." ('580 Patent col. 20 l. 15–25; '790 Patent col. 20 l. 36–40; '248 Patent col. 20 l. 15–20; '989 Patent col. 21 l. 1–6; '983 Patent col. 21 l. 32–38; *see also* '683 Patent col. 20 l. 20–29; '940 Patent col. 21 l. 59–65.) In the '580, '683, and '248 Patents, the "XR component [or components] releases [or release] the topiramate contained therein such that greater than or equal to about 80% of the topiramate is released in vitro in less than or equal to about 4 hours," ('580 Patent col. 20 l. 50–54; *see also* '683 Patent col. 20 l. 26–29; '248 Patent col. 20 l. 47–50), or such that "greater than or equal to about 80% of the topiramate is released in vitro in less than or equal to about 12 hours," ('248 Patent col. 22 l. 14–16).[8] In the '989, '940, and '983 Patents, the "XR component exhibits

[8] "In vitro" rate of drug release is the typical way to measure drug release rates. ('580 Patent col. 3 l. 58–59.) "In vitro" refers to "a quantity of drug release from the dosage form per unit time measured under appropriate conditions and in a suitable fluid." (*Id.* col. 3 l. 58–60.)

a maximum plasma concentration of topiramate in vivo at 16 or more hours after a single initial dose." ('989 Patent col. 21 l. 33–35, col. 22 l. 67–col. 23 l. 3; '940 Patent col. 22 l. 25–27, col. 24 l. 25–28; '983 Patent col. 21 l. 65–67, col. 23 l. 32–35.) In the '790 Patent, "the formulation exhibits an in vivo steady state maximum plasma concentration of topiramate at 3 or more hours after administration." ('790 Patent col. 21 l. 1–3, col. 22 l. 20–23.)[9]

The claim language alone does not provide a clear meaning of the term "extended release component," so the Court looks to the specification. *See Phillips*, 415 F.3d at 1315. The patent is entitled "Sustained-Release Formulations of Topiramate," and is characterized by the "sustained release" of topiramate along a "pre-determined release profile." ('580 Patent col. 2 l. 6–10.) The "sustained release" distinguishes the Trokendi patents from Topamax, an "immediate release formulation" where the "topiramate is rapidly absorbed with plasma drug concentrations peaking in approximately 2 hours." (*See* '580 Patent col. 1 l. 31, col. 5 l. 24–47.) The sustained release is "achieved by incorporation into the formulation of an extended release component (XR) and an optional immediate release component (IR)." (*Id.* col. 6 l. 9–17.) Extended release components appear in all of the Trokendi patents, both asserted and not asserted, and, unlike immediate release components, are not optional. (*See generally* '580 Patent; '683 Patent; '248 Patent; '989 Patent; '940 Patent; '983 Patent; '790 Patent; '004 Patent; '191 Patent; '576 Patent.) Thus, the extended release components are key to achieving the "sustained release formulations of topiramate" covered by the Trokendi patents.

The amount of each component (XR and IR) is "determined according to the purpose of administration and a pre-determined release profile." ('580 Patent col. 6 l. 18–22.) The "pre-

[9] Unlike "in vitro," which measures the quantity of drug release per unit of time in a controlled setting, an "in vivo" measurement is based on quantity of topiramate in the human body, measured by blood plasma concentration. (*See* '580 Patent col. 5 l. 19–47; *see also* Tr. 35:14–17.)

determined release profile" differs according to the purpose of the administration. (*See id.* col. 2 l. 46–58.) For example, "when a fast onset of action followed by sustained release is preferred, as . . . in the cases of a breakthrough migraine episode," a dosage form may include an immediate release topiramate formulation "coating on the outside [of] a capsule that contains within it other populations of topiramate such as extended release topiramate." (*Id.* col. 11 l. 4–24.)

The specification provides a meaning for "XR component." It states that "[t]he XR component of the formulation of the present invention releases topiramate in a continuous manner and is adjusted in such a way that 80% of the active ingredient is released in vitro in the predetermined period of time." (*Id.* col. 6 l. 30–33.)

The Court construes "extended release component" to mean, as stated expressly in the specification, a component that "releases topiramate in a continuous manner and is adjusted in such a way that 80% of the active ingredient is released in vitro in the predetermined period of time." (*Id.* col. 6 l. 30–33.) The "predetermined period of time" refers to the period of time necessary to achieve the "predetermined release profile" for the particular "sustained release" formulation. (*See id.* col. 2 l. 46–58, col. 11 l. 4–24.)

This construction is consistent with the sentence following the definition for "XR component," which states, "[b]y way of example, and by no means limiting the scope of the invention, the period of time may be not more than 24 hours, not more than 16 hours, not more than 12 hours, not more than 8 hours, or not more than 4 hours, depending on desired attributes of the final product." (*Id.* col. 6 l. 34–38.) This construction also allows, as the specification and claims contemplate, the "predetermined release profile" to differ based on the purpose of the

dosage administration. (*See, e.g.*, '580 Patent col. 20 l. 50–54; '248 Patent col. 22 l. 15–16; '580 Patent col. 11 l. 4–24.)[10]

The Court does not adopt either Plaintiff's or Defendants' constructions, both which overlook the specification language describing "XR component." Plaintiff's construction broadens the meaning of the term by removing language included in this description. (*See* '580 Patent col. 6 l. 30–33; Pl.'s Opening Br. 12–14); *see also Nat'l Oilwell Varco*, 2011 WL 3648532, at *4 (rejecting construction that is an "improper attempt to broaden the claim").

The Court also rejects Defendants' proposed construction, which seeks to construe "extended release component" as the inverse of "immediate release component." A "negative limitation" must be supported by the words of the claims, or "any express disclaimer or independent lexicography in the written description that would justify adding that negative limitation." *Omega Eng'g, Inc.*, 334 F.3d at 1323; *see also Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1350–51 (Fed. Cir. 2012) (construing a claim to have a limitation that a particular composition "contain[ed] no sucralfate," where the claim language stated so and which was supported by the specification "expressly list[ed] the disadvantages of using sucralfate"). Unlike in *Santarus*, where the claim expressly included the negative limitation and the specification repeatedly supported that limitation, 694 F.3d at 1350–51, here, the claim language and the specification do not indicate that an "extended release component" should be defined as "not an immediate release component," as Defendants assert, (Defs.' Opening Br. 20).

[10] The Court does not reach the prosecution history for this term because the meaning of this term is clear based on the claim language and specification. *See Chiesi USA, Inc. v. Aurobindo Pharma USA, Inc.*, Civ. No. 19-18756, 2021 WL 4860327, at *6 (D.N.J. Oct. 19, 2021) (declining to consider the prosecution history, determining that "the statements made during prosecution do not overcome the weight of the specification's repeated descriptions of the invention . . .").

The Court notes (and Plaintiff does not dispute) that the intrinsic evidence indicates that "extended release" and "immediate release" components are different from each other. (*See* Tr. 45:17–21, 47:1–4.) These differences, however, do not justify importing a negative limitation into the construction of "extended release component," particularly where the intrinsic evidence provides an affirmative description of this term. *See Intel Corp. v. Qualcomm Inc.*, 21 F.4th 801, 812 (Fed. Cir. 2021) (noting that, before construing a claim with an "entirely [] negative" construction, the Patent Trademark Appeals Board should conduct a "substance-focused analysis" of the intrinsic evidence, "which seem[ed] likely to support an affirmative construction in place of the Board's purely negative one"). Thus, rather than define "extended release component" as the inverse of "immediate release component," the Court construes "extended release component" based on definition included in the written description.

5. Term Group No. 5: "A Coating Material Selected from the Group Consisting of Cellulosic Polymers and Acrylic Polymers" and "Comprising a Coating Material Selected from the Group Consisting of Cellulosic Polymers and Acrylic Polymers"

Claim Term	"A coating material selected from the group consisting of cellulosic polymers and acrylic polymers" "Comprising a coating material selected from the group consisting of cellulosic polymers and acrylic polymers"
Plaintiff's Proposed Construction	Requires no construction — plain and ordinary meaning "A coating material selected from the group consisting of cellulosic polymers and acrylic polymers" "Comprising a coating material selected from the group consisting of cellulosic polymers and acrylic polymers"
Defendants' Proposed Construction	"A coating material for each extended release component selected from the group consisting of cellulosic polymers and acrylic polymers" "Comprising a coating material for each extended release component selected from the group consisting of cellulosic polymers and acrylic polymers"
Court's Construction	'248, '989, '940, '983, and '790 Patents: Requires no construction — plain and ordinary meaning

	'580 Patent: the phrase, "a release controlling coating specific for its component and comprising a coating material selected from the group consisting of cellulosic polymers and acrylic polymers" shall be construed as: "a release controlling coating that is both specific for its component and also comprising a coating material selected from the group consisting of cellulosic polymers and acrylic polymers"

a. Parties' Arguments

The principal disagreement is whether, in claims that have "at least two" extended release components, *each* extended release component must have "a coating material selected from the group consisting of cellulosic polymers and acrylic polymers." (Pl.'s Opening Br. 15–16, Defs.' Opening Br. 26–28.) Plaintiff argues that the plain language of the claims "does not specify or require that 'each component' comprise the recited cellulosic and acrylic polymers," and that, "[i]f the applicants wanted to include that requirement, they would have explicitly said so in the claim itself." (Pl.'s Opening Br. 16.) Plaintiff contends that the plain language of the claims "dictates that the requirements for a release controlling coating and for the recited polymers are separate requirements." (*Id.*)

Defendants argue that a "skilled artisan would understand the claims reciting two XR components to describe two XR components that each have a coating material consisting of a cellulosic polymer or an acrylic polymer." (Defs.' Opening Br. 27.) Defendants contend that "[t]he independent claims reciting the disputed claim terms reference them in the context of an XR component," and thus, the "XR component(s) [] comprise the coating material consisting of cellulosic polymers and acrylic polymers." (*Id.* (citing '580 Patent, claim 1; '248 Patent, claim 1; '989 Patent, claim 14; '940 Patent, claim 14; '983 Patent, claim 13; and '790 Patent, claim 1).) Defendants further argue that the prosecution history, where applicants distinguished their patents from the prior art based on the XR components being "coated with a release controlling coating *specific for its population*," further supports their construction. (*Id.* at 27–28 (citing '576 Patent

Prosecution History, Amendment and Reply under 37 C.F.R. § 1.111, Applicant Remarks 27 (July 27, 2010) (emphasis in original).)

b. Court's Construction

This term appears in several contexts in the asserted patents. The '580 Patent claims "at least two different extended release topiramate-containing components, wherein each component comprises a release controlling coating specific for its component and **comprising a coating material selected from the group consisting of cellulosic polymers and acrylic polymers** . . . ." ('580 Patent col. 20 l. 20–25 (disputed term bolded).)

The '248, '989, '940, and '983 Patents claim "an extended release (XR) topiramate-containing component, **comprising a coating material selected from the group consisting of cellulosic polymers and acrylic polymers** . . . ." ('248 Patent col. 20 l. 19–50; '989 Patent col. 21 l. 5–8, col. 22 l. 38–col 23 l. 3; '940 Patent col. 21 l. 64–67, col. 23 l. 31–34; '983 Patent col. 21 l. 37–40 (disputed term bolded).)

The '790 Patent claims "at least two extended release (XR) topiramate-containing components, wherein each component **comprises a coating material selected from the group consisting of cellulosic polymers and acrylic polymers** . . . ." ('790 Patent col. 20 l. 39–43 (disputed term bolded).)

The principal dispute is whether each extended release component in the asserted claims must contain the specified coating. (Defs.' Opening Br. 26–28; Pl.'s Opening Br. 15–16.) This construction is necessary only for the '580 Patent because the claim language in the other asserted patents is clear that each extended release component must comprise the coating. The '248, '989, '940, and '983 Patents claim only one extended release component, and thus, the phrase "comprising a coating material selected from the group consisting of cellulosic polymers and

acrylic polymers" can only apply to that component. (*E.g.*, '983 Patent col. 21 l. 37–40.) The plain language of the '790 Patent is also clear on this point, because it claims "at least two extended release (XR) topiramate-containing components, wherein *each component* comprises a coating material selected from the group consisting of cellulosic polymers and acrylic polymers." ('790 Patent col. 20 l. 39–43 (emphasis added).) Thus, the plain language of the claims in the '248, '989, '940, '983, and '790 Patents is unambiguous that each of the extended release components claimed contains the specified coating. In the context of these patents, no further construction is necessary, and the plain meaning of this phrase governs the meaning of the disputed term.

The Court turns to the'580 Patent, which claims "at least two extended release topiramate-containing components, wherein each component comprises a release controlling coating specific for its component and comprising a coating material selected from the group consisting of cellulosic polymers and acrylic polymers." ('580 Patent col. 20 l. 20–25.) For the following reasons, the Court determines that the disputed phrase applies to each extended release component.

First, the most natural reading of the claim language is that the "release controlling coating" is modified by both the phrase "specific for its component" and also the phrase "comprising a coating material selected from the group consisting of cellulosic polymers and acrylic polymers." The "and" is a conjunctive article that links the phrases together as requirements for the "release controlling coating." *See Medgraph, Inc. v. Medtronic, Inc.*, 843 F.3d 942, 949–50 (Fed. Cir. 2016) (noting that, unless the specification indicates otherwise, the use of the term "and" is conjunctive).

Second, the Court rejects Plaintiff's proposed construction because it renders the disputed phrase superfluous. *See Wasica Finance GmbH v. Continental Automotive Systems, Inc.*, 853 F.3d 1272, 1288 n.10 (Fed. Cir. 2017) ("It is highly disfavored to construe terms in a way that renders

them void, meaningless, or superfluous.") Plaintiff argues that the claim does not specify that "'each component' comprise the recited cellulosic and acrylic polymers," and that, "[i]f the applicants wanted to include that requirement, they would have explicitly said so in the claim itself." (Pl.'s Opening Br. 16.) Plaintiff does not explain why this phrase is in the claim if it is not a "requirement" for each component. If the patentee wanted the coating to be "optional," they would have said so, as they did for other optional components. (*E.g.*, '580 Patent col. 20 l. 25 (stating that the immediate release component was "optional").) Similarly, if the patentee wanted the coating to apply to only one of the extended release components, they would have said so, as they did in other claims. (*See, e.g.*, '580 Patent col. 20 l. 58–63 (in a claim dependent on claim 1, stating that "at least one of the two XR components further comprises a binder . . .") Thus, looking to both the independent and dependent claims, Plaintiff's proposed construction renders the disputed phrase superfluous. *See Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1119 (Fed. Cir. 2004) (noting that all terms in a claim should be given meaning).

Third, the specification supports the Court's construction that the disputed term modifies "release controlling coating." The specification states that a "release controlling coating" is "a coating that modifies and controls the release of topiramate from the beads," (*See* '580 Patent col. 6 l. 39–42), where the "beads" include "any structural units that may be incorporated into an oral dosage form," (*id.* col. 4 l. 40–43). The release controlling coating is "population-specific in the sense that the rate of release of topiramate from every bead population is controlled by at least one parameter of the release controlling coating." (*Id.* col. 7 l. 13–17.) The specification also contemplates the inclusion of cellulosic and acrylic polymers in the coating, stating, "[t]he coating material is preferably selected from a group comprising cellulosic polymers, such as [lists examples]; polyvinyl alcohol; acrylic polymers such as [lists examples], and other water-based or

solvent-based coating materials." (*Id.* col. 7 l. 6–13.) Thus, reading the claims in light of the specification, *see Phillips*, 415 F.3d at 1315, it makes sense to construe the "release controlling coating" in the '580 Patent as *both* (1) "specific for its component" (because the '580 Patent includes multiple extended release components, (*see id.* col. 20 l. 20–21, 50–54)); and also (2) "comprising a coating material selected from the group consisting of cellulosic polymers and acrylic polymers" (because the specification teaches that the release controlling coating may include these polymers, (*see id.* col. 7 l. 6–13)).[11] This construction also makes the '580 Patent consistent with the other patents in suit that require each XR component to comprise the specified "release controlling coating." (*E.g.*, '248 Patent col. 20 l. 19–22, col. 21 l. 37–40; '989 Patent col. 21 l. 5–8, col. 22 l. 38–41; '940 Patent col. 21 l. 64–67, col. 23 l. 31–34; '983 Patent col. 21 l. 37–40, col. 23 l. 4–7; '790 Patent col. 20 l. 39–43, col. 21 l. 57–61.)

Thus, the Court construes the "release controlling coating" in the '580 Patent as *both* specific for its component *and* comprising a coating material selected from the group of cellulosic polymers and acrylic polymers. The Court confines this construction to the '580 Patent. The Court construes the disputed phrases in the '248, '989, '940, '983, and '790 Patents as clear based on their plain and ordinary meanings, and no further construction is necessary.

IV. CONCLUSION

For the foregoing reasons, the Court construes the disputed terms as follows. An accompanying Order follows.

[11] The Court does not reach the prosecution history because the meaning of the disputed claim terms are clear from the claims and specification.

"Release topiramate in a continuous manner" "Releases topiramate in a continuous manner" "Released topiramate in a continuous manner" "Released . . . continuously"	Requires no construction — plain and ordinary meaning "Release topiramate in a manner without interruption" "Releases topiramate in a manner without interruption" "Released topiramate in a manner without interruption" "Released . . . without interruption"
"Immediately and continuously"	Requires no construction — plain and ordinary meaning "Without delay and without interruption"
"Immediate release"	"Releases greater than or equal to about 80% of the pharmaceutical agent in less than or equal to about 1 hour"
"Extended release (XR) component" or "extended release component" "Extended release (XR) topiramate-containing component(s)" or "extended release topiramate-containing component(s)"	"A component that releases topiramate in a continuous manner and is adjusted in such a way that 80% of the active ingredient is released in vitro in the predetermined period of time"
"A coating material selected from the group consisting of cellulosic polymers and acrylic polymers" "Comprising a coating material selected from the group consisting of cellulosic polymers and acrylic polymers"	'248, '989, '940, '983, and '790 Patents: Requires no construction — plain and ordinary meaning '580 Patent: the phrase, "a release controlling coating specific for its component and comprising a coating material selected from the group consisting of cellulosic polymers and acrylic polymers" shall be construed as: "a release controlling coating that is both specific for its component and also comprising a coating material selected from the group consisting of cellulosic polymers and acrylic polymers"

Date: December 1, 2022

GEORGETTE CASTNER
United States District Judge